IL-6 Test Kit User Manual

(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

IL-6 Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit

5 tests/kit

25 tests/kit

50 tests/kit

100 tests/kit

[INTENDED USE]

IL-6 Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of IL-6 (Interleukin-6) in human serum and .IL-6 can be synthesized by a variety of cells, including activated T cells and B cells, Mononuclear-Macrophages, Endothelial cells, Epithelial cells, and Fibroblasts.

The elevation of IL-6 in inflammatory responses precedes other cytokines, as well as CRP , and lasts longer, so it can be used to aid the early diagnosis of acute infections.After bacterial infection, IL-6 levels rise rapidly and will peak in 2 hours, which is consistent with the severity of infection.IL-6 can also be used to assess infection severity and prognosis.Dynamic observation of IL-6 levels can also help to understand the progression of infectious diseases and response to treatment.The commonly used detection methods in clinic and laboratory are chemiluminescence and immunofluorescence.

[TEST PRINCIPLE]

IL-6 Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction.

Two strains of monoclonal antibodies with high specificity and sensitivity were used, in which IL-6 mouse monoclonal antibody 1 was captured and coated in the test area on the nitric acid fiber membrane. IL-6 mouse monoclonal antibody 2 was labeled as fluorescent microspheres and fixed on the binding pad.The antigen in the sample was combined with the fluorescent microsphere labeled with IL-6 mouse monoclonal antibody 2 in the binding pad. The complex was then captured by IL-6 mouse monoclonal antibody 1 fixed on the test area to form a fluorescent microsphere sandwich structure.The fluorescent particle complex labeled with chicken IgY in the binding pad binds to the sheep anti-chicken IgY fixed on the nitrocellulose membrane to form the quality control area.The content of IL-6 in human blood can be quantitatively detected by measuring and analyzing the compound with supporting instruments.

[MAIN COMPONENTS]

1. IL-6 test strip in a sealed pouch with desiccant..... 25 tests
2. QR code card for calibration..... 1 piece
3.User Manual..... 1 piece
4.Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.

Test strip should be used within 1 hour once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-1100 Dry Fluorescence Immunoassay Analyzer
3. LS-2000 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Dry Fluorescence Immunoassay Analyzer
6. LS-7000 Dry Fluorescence Immunoassay Analyzer
7. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer
8. LS-7800 Automatic Microfluidic and Dry Fluorescence Immunoassay Analyzer
9. LS-3000 Automatic Fluorescence Immunoassay Analyzer
10. LS-3100 Automatic Fluorescence Immunoassay Analyzer

[**SAMPLE REQUIREMENT]**

1. Used for human serum. Other bodily fluids and samples may not get the accurate result.

2. At room temperature, the test should be performed within 2 hours after the sample collection.Serum sample can be stored at 2℃-8℃ for 3 days at most. If more than 3 days, it should be stored at -20℃. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.

3.Avoid using microbial contamination samples.

4.The frozen samples shall be completely melted, reheated and mixed before being used.Repeated freeze-thaw should be avoided. It is recommended that samples be freeze-thaw not more than once. If there are sediments in thawed samples, centrifuge the samples before testing them.

[TEST PROCEDURE]

1. Collect samples according to user manual.

2. Before the test, the sample and test strip should be recovered to room temperature (15℃-30℃).

3.Perform QR code calibration when necessary (Details refer to User Manual)

4. On the main interface of analyzer, press “Test” icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to User Manual)

5.Remove test strip from sealed pouch and put it on a clean table, horizontally placed.

6.Using pipette to drop 100μL sample into the sample port in the test strip.

7. **Reaction Time: 15 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click “Test”.

For panel outside: After reaction time 15 minutes is elapsed, insert the

test strip into the analyzer and then click “Test”.

7. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Reference Range: IL-6：≤ 10 pg/mL

Through the determination of interleukin-6 (IL-6) content in the whole blood, serum and plasma samples of 180 healthy people, the following reference interval was obtained after the statistical analysis of 95% distribution range.

It is recommended that each laboratory establish its own reference rang for the population it serves.

[INTERPRETATION OF RESULT]

1.If the test result of the sample is more than 2000pg/mL, the analyzer displays “>2000pg/mL”, and if the result is less than 4.8pg/mL, the analyzer displays “<4.8pg/mL”. Specific data can be exported through related software as needed.

2.When the sample concentration exceeds the detection limit, the maximum dilution ratio is 2 times when the sample is diluted with calf serum or negative sample.

[LIMITATION]

1. The test result of this kit are only one of the diagnostic aids for the clinicians.

2.Samples containing interfering substances will affect the test results,and the maximum allowable concentration are:2mg/mL bilirubin, 3mg/mL hemoglobin, 10mg/mL triglyceride.

[PRODUCT PERFORMANCE]

1. Lower Detection Limit: 4.8pg/mL.

3. Accuracy:Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.

4. Within-Run Precision: ≤15%.

5. Between-Run Precision: ≤15%.

6..Measuring Range: 5pg/mL-2000 pg/mL,r≥0.990

[PRECAUTIONS]

1. IVD:In vitro diagnostic medical device.

2.After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.

4. The damaged test strip or package cannot be used.

5.All sample from patients should be treated as potential sources of infection.

6. Used strips should be properly disposed according to local regulations to avoid contaminnation.

[REFERENCES]

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Revision Date: November 11, 2020
Version Number: 0.1
Production date and expiration see the label.